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EXAMINER

KERR, KATHLEEN M

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 03/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/537,710

Applicant(s)

DAHLQVIST ET AL.

Examiner

Kathleen M Kerr

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23,25 and 28-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-23 25 28-33 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Application Status

1. Upon receiving a supplemental written restriction requirement (Paper No. 21 mailed February 19, 2003), Applicants telephoned the Examiner concerned about its clarity and the distinctness between the species noted. The Examiner agreed to mail a supplemental action.

The instant Office action is a supplemental restriction requirement that better groups the instant claims; said action is the second supplemental restriction requirement. Said supplemental requirement is at the discretion of the Examiner (see M.P.E.P. § 802 and 37 C.F.R. § 1.142) and is deemed appropriate and necessary in view of the complex subject matter of the instant claims and the extensive searching required to identify prior art relating to the instant subject matter.

Applicants need only respond to the instant Office action in response to the restriction requirement.

Restriction

2. Restriction to one of the following inventions (Groups) is required under 35 U.S.C. §

121. First presented are SuperGroups which are further broken down into Groups below:

SuperGroup A. Claims 1-6, drawn to acyltransferase enzymes, classified in class 435, subclass 193.

SuperGroup B. Claims 7-23, 28, and 29, drawn to nucleotide sequences, vectors, and host cells, classified in class 435, subclass 252.3.

SuperGroup C. Claims 16, 17, 19-23, drawn to transgenic animals, classified in class 800, subclass 13.

SuperGroup D. Claims 16-23, drawn to transgenic plants, classified in class 800, subclass 295.

SuperGroup E. Claim 25, drawn to triacylglycerols, classified in class 554, subclass 173.

SuperGroup F. Claims 30-32, drawn to processes for producing triacylglycerol using particular nucleotide sequences and/or host cells, classified in class 435, subclass 159.

SuperGroup G. Claim 33, drawn to processes for producing triacylglycerol using particular enzymes, classified in class 435, subclass 159.

Art Unit: 1652

SuperGroup E is itself only a single Group. In each of SuperGroups A, B, C, D, F, and G, the following Groups are found:

- Group 1.** related to *Saccharomyces cerevisiae* sequences, SEQ ID NOs: 1, 2, 16, 19, 20, 21, 22
- Group 2.** related to *Arabidopsis thaliana* sequences, SEQ ID NOs: 4, 5, 6, 10, 11, 14, 15, 17, 18, 24, 25, 29, 30
- Group 3.** related to *Zea mays* sequences, SEQ ID NOs: 7, 8, 26, 27
- Group 4.** related to *Schizosaccharomyces pombe*, SEQ ID NOs: 3, 13, 23
- Group 5.** related to *Neurospora crassa*, SEQ ID NOs: 9, 28
- Group 6.** related to *Lycopersicon esculentum*, SEQ ID NOs: 12, 31

Thus, the six Groups for each of SuperGroups A-D and F and G (six SuperGroups) = 36 individual Groups plus the single Group of SuperGroup E = a total of 37 Groups or 37 distinct inventions in the pending claims. Applicants must choose ONE of said Groups; to do so, Applicants must elect a single SuperGroup (A-G) AND a Group (1-6); if SuperGroup E is elected, no Group is required for election.

3. The inventions are distinct, each from the other because of the following reasons:

Within each SuperGroup, the various Groups (1-6) are related by virtue of being PDAT sequences. Each SEQ ID NO (DNA along with its encoded protein) is distinct from every other sequence based on the different structural characteristics; no common consensus sequence is disclosed to describe a genus of all PDAT sequences across all the disclosed species. Thus, each of these different sequences must be searched separately in databases using searches that are not co-extensive. However, the Examiner has grouped SEQ ID NOs from the same species together (see Group headings above) and has subjected groups with multiple sequences in one species to an election of species below.

Art Unit: 1652

The nucleotide sequences of SuperGroup B are related to the enzymes of SuperGroup A by virtue of the fact that the nucleotide sequences encode the enzymes. The nucleotide sequences have utility for the recombinant production of the enzyme in a host cell. Although the nucleotide sequences and the enzyme are related, they are distinct inventions because the enzyme product can be made by other and materially distinct processes, such as purification from a natural source. Furthermore, the nucleotide sequences can be used for processes other than the production of enzyme, such as nucleic acid hybridization assays. Therefore, SuperGroups A and B are patentably distinct. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper since the search of more than one class/subclass in a single application is considered unduly burdensome on the Office.

The enzymes of SuperGroup A are related to the transgenic animals of SuperGroup C and the transgenic plants of SuperGroup D by virtue of the DNA that encodes the enzymes and is the transgene in the organisms. These Groups are distinct for the reasons noted above between the nucleotide sequences and the enzymes. Thus, SuperGroup A is patentably distinct from SuperGroups C and D. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper since the search of more than one class/subclass in a single application is considered unduly burdensome on the Office.

The enzymes of SuperGroup A and the triacylglycerol of SuperGroup E are related because the enzymes can be used to produce the triacylglycerol. However, these products are wholly distinct having entirely distinct structures, functions, methods of production, etc. Thus,

Art Unit: 1652

SuperGroups A and E are patentably distinct. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper since the search of more than one class/subclass in a single application is considered unduly burdensome on the Office.

The enzymes of SuperGroup A are related to the methods of SuperGroup F because the enzymes are encoded by DNA used in the methods. However, the enzymes themselves are neither used nor produced in the claims methods. Thus, SuperGroups A and F are patentably distinct. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper since the search of more than one class/subclass in a single application is considered unduly burdensome on the Office.

SuperGroups A and G are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the enzymes of SuperGroup A can be used in a materially different process of using that product, such as in the *in vivo* production of antibodies and/or in enzyme activity assays. Thus, SuperGroups A and G are patentably distinct. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper since the search of more than one class/subclass in a single application is considered unduly burdensome on the Office.

Art Unit: 1652

The nucleotide sequences of SuperGroup B are related to the transgenic animals and plants of SuperGroups C and D, respectively, as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (M.P.E.P. § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the nucleotide sequence does not require the particulars of a transgenic plant or animal since it can be used in bacterial host cells. The subcombination has separate utility such as production of triacylglycerol in plants. Thus, SuperGroups C and D are patentably distinct from SuperGroup B. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper since the search of more than one class/subclass in a single application is considered unduly burdensome on the Office.

The nucleotide sequences and transgenic organisms of SuperGroups B-D and the triacylglycerol of SuperGroup E are related because the nucleotide sequences encode the enzymes that can be used to produce the triacylglycerol. However, these products are wholly distinct having entirely distinct structures, functions, methods of production, etc. Thus, SuperGroups B-D are patentably distinct from SuperGroup E. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper since the search of more than one class/subclass in a single application is considered unduly burdensome on the Office.

Art Unit: 1652

SuperGroups B and F are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the nucleotide sequences of SuperGroup B can be used in a materially different process of using that product, such as in the *in vitro* production of the encoded enzyme. Thus, SuperGroups B and F are patentably distinct. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper since the search of more than one class/subclass in a single application is considered unduly burdensome on the Office.

The nucleotide sequences of SuperGroup B are related to the methods of SuperGroup G because the enzymes are encoded by DNA are used in the methods. However, the nucleotide sequences themselves are neither used nor produced in the claims methods. Thus, SuperGroups B and G are patentably distinct. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper since the search of more than one class/subclass in a single application is considered unduly burdensome on the Office.

The transgenic plants of SuperGroup C and the transgenic animals of SuperGroup D are related by virtue of having the same transgene in the organisms. However, these SuperGroups are distinct by virtue of their wholly different structures and functions. Thus, SuperGroups C and D are patentably distinct. Because these inventions are distinct for the reasons given above

Art Unit: 1652

and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper since the search of more than one class/subclass in a single application is considered unduly burdensome on the Office.

SuperGroups C and D are related to SuperGroups F and G as the relationship of SuperGroup B with SuperGroups F and G is noted above. They are distinct for the same reasons noted above and would require an unduly burdensome search for the reasons noted above.

Notice of Possible Rejoinder

4. The Examiner notes that if product claims are found to be allowable, then process claims, which are directed to processes of making or using the patentable product, previously withdrawn from consideration as a result of a restriction requirement, would now be rejoined pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86; see also M.P.E.P. § 821.04, *In re Ochiai*, and *In re Brouwer*). Claims in SuperGroup F are methods of using claims in SuperGroup B and claims in SuperGroup G are methods of using claims in SuperGroup A. Since process claims would be rejoined and fully examined for patentability under 37 C.F.R. § 1.104, Applicants are instructed to amend said claims as deemed necessary according to rejections made against the elected claims. The following is an example of possible rejoinder scenarios:

Elected and Allowable

Rejoin

SuperGroup B (Group 1)

SuperGroup F (Group 1)

SuperGroup A (Group 3)

SuperGroup A (Group 3)

On no occasion will the "Groups" be rejoined (i.e., all the different sequences be examined) since they are distinct for the reasons noted above.

Election of Species

5. Before the election of species is presented, the Examiner notes that the sequence listing and description, as amended, is confusing as to which DNAs encode which proteins, thus, discerning species was difficult for the Examiner. Particularly, the Examiner notes that the amendment to pages 35-37 of the specification deleted the description of 16 sequences and added the description of only 11 sequences (omitting 5 sequence descriptions previously filed). Applicants are requested to double-check this amendment.

Generally speaking, a “species” herein is any specific DNA sequence and its directly encoded protein only. Such a species is distinct from other specific DNAs and their encoded proteins, regardless of their source (i.e., even if they are both from *S. cerevisiae*), by virtue of their distinct and characteristic structures since no consensus sequence that can define a genus of DNAs is disclosed.

This application contains claims directed to the following patentably distinct species of the claimed invention:

- Group 1 species = SEQ ID NOs: (1 and 2), (16), (19 and 20), and (21 and 22)
- Group 2 species = SEQ ID NOs: (4 and 18 and 24), (5 and 6 and 25), (10, and 14, and 17), (11 and 15), (29), and (30)
- Group 3 species = SEQ ID NOs: (7 and 8) and (26 and 27)
- Group 4 species = SEQ ID NOs: (3 and 13) and (23)
- Group 5 species = SEQ ID NOs: (9) and (28)
- Group 6 species = SEQ ID NOs: (12) and (31)

*The Examiner notes that some of these species may actually be the same because some of the SEQ ID NOs may be duplicated (based on the same sequence length). All duplicate sequences in the listing should be removed. Again, the Examiner notes that a “species” is any DNA and its exactly encoded protein; this “species” is what must be elected. If the elected species is not

Art Unit: 1652

found in the prior art, an additional species in that same Group will be examined on first action. For this reason and because the "species" are confusing based on the confusing sequence listing, Applicants are required to define the different species in their elected Group. If said additional species is not found in the prior art, any additional species will be examined...and so on...until the Group is fully searched (if none of the sequences are in the prior art). Additional Groups will NOT be searched, only additional species within the elected Group.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species (as defined by parentheses above) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 1-23 and 28-33 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

Art Unit: 1652

examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103(a) of the other invention.

Election

6. A telephone call was made to Daniel Kim on March 6, 2003 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. § 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(i).

Conclusion

7. A complete response to the instant Office action must include and election of an invention, which is defined by **a SuperGroup (A-G) AND a Group (1-6)** (unless SuperGroup E is elected). A complete response must **ALSO** include **an election of species** within the elected Group (1-6) (unless SuperGroup E is elected) of a SEQ ID NO of a DNA and its exactly encoded protein. Thus, Applicants response must include **(1)** an elected SuperGroup, **(2)** an elected Group, and **(3)** an elected species and the definition of species within the elected Group.

Art Unit: 1652

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (703) 305-1229.

The examiner can normally be reached on Monday through Friday, from 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

KMK

March 6, 2003

